RELEASE INSTRUCTIONS (RI) 0047497

DOCUMENT NO.: WHC-CM-5-4

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TO:	TITLE: Laboratories Administration
D. A. Isom H6-08 Copy #072	RELEASE NO.: 064 DATE PREPARED: July 14, 1997
I have entered this release into the document per instructions. DA Isom 7/21/97 Signature Date	If you have any questions about this release contact: Jean Feaster Phone: 373-4426

INSTRUCTIONS

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SECTION NO. AND TITLE(S)	REMOVE			INSERT		
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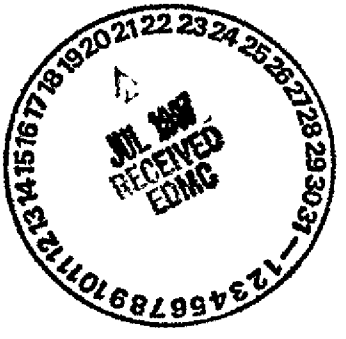
IMPLEMENTATION NOTICE

(ROUTE A COPY OF THE IMPLEMENTATION NOTICE TO ALL USERS OF THIS COPY OF THE MANUAL)

Section 3.34 replaces Section 1.4 in WHC-CM-5-3 manual.

Section 8.8 revised to current operating practices.

Section 11.10 replaced by LAP-125-100.



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Statements of Work for Hanford Analytical Services	Approved by J. E. Hyatt, Manager Hanford Analytical Services
Author: Organization:	B. M. Colley Sample Management

1.0 PURPOSE

The purpose of this procedure is to describe development, revision, review, approval, and issuance of Statements of Work (SOW) used to obtain analytical services from off- and on-site analytical laboratories by the Sample Management Office (SMO).

2.0 SCOPE

The scope of this procedure encompasses SOWs written for the acquisition of analytical laboratory services by the SMO.

3.0 REQUIREMENTS

Customer
Any organization that requires analytical laboratory services.

Statement of Work (SOW)
A formal SMO document defining administrative, technical and quality assurance requirements to an off or on-site contractor for the acquisition of analytical laboratory services.

4.0 REQUIREMENTS

The SOW for analytical laboratory services are generated in accordance with quality assurance requirements set forth in WHC-CM-4-2, *Quality Assurance Manual*, Section QR 4.0, "Procurement Document Control."

5.0 RESPONSIBILITIES

5.1 SMO Project Coordinator

- Compiles information from customer(s) on project and/or analytical requirements to generate an SOW in accordance with this procedure.
- Initiates the SOW review and approval process and obtains the necessary approvals.

5.2 SMO Contract Administrator

- Maintains the original SOW and SOW/contract file.
- Maintains SOW document number log.

5.3 SMO Manager

- Oversight of the laboratory analytical services provided to SMO and customers.
- Reviews and approves SOW.

5.4 Project Quality Assurance (QA) Representative

- Reviews and approves SOWs generated by the SMO for analytical laboratory service.

5.5 Customer/Technical Coordinator

- Provides technical information through formal documentation (i.e., letter outlining requirements, work plan, sampling plan, or other documentation) to the SMO Project Coordinator.

5.6 Contract Technical Representative

- Interfaces with the Procurement organization to obtain contracted services as needed to meet SOW requirements.

6.0 PROCEDURE

The SMO Project Coordinator prepares the SOW. The requirements of the SOW are provided by the Customer/Technical Coordinator through work plans, sample plans, characterization plans, Data Quality Objective process, and/or other pertinent documentation.

Statements of Work consist of the following topics/requirements:

- cover page
- services required
- technical requirements
- quality assurance/quality control
- analytical deliverables
- document control
- sample management
- contract management and deliverables
- organization of technical proposal.

Figures 1 and 2 of this procedure describe the form and content of each topic/requirement listed above.

6.1 Preparation

6.1.1 The SMO Project Coordinator obtains a SMO document number from the SMO Contract Administrator for the SOW. The number consists of the following format:

WMX-SOW-XX-0001

0001	=	Consecutive number
XX	=	Current Calendar Year
SOW	=	Document Type (SOW)
WMX	=	Company Identifier

6.1.2 The SOW document numbers are issued, controlled, and maintained by the Contract Administrator through the use of a SOW document number log.

6.2 Review Cycle

The SMO Project Coordinator processes the SOW in the following manner:

6.2.1 Submit DRAFT SOW to SMO and other contractors for peer review.

6.2.2 Disposition comments.

6.2.3 Submit the SOW with Review Comment Record to the appropriate individuals for review and comment.

6.2.4 Resolve all comments, and obtain the required approval signatures.

6.3 Revision

The customer/technical coordinator contacts the SMO Project Coordinator with SOW scope changes (technical or administrative). The SMO Project Coordinator makes the required changes and follows the steps in Section 6.2 for amending the SOW.

6.4 Distribution

The SMO Contract Administrator distributes the SOW to the following individuals:

- SMO Project Coordinator
- SMO Manager
- Quality Assurance Representative

- Customer/Technical Coordinator
- Contract/project file
- Procurement (if applicable)
- Any other contractor using these services.

7.0 RECORDS

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

8.0 DESIGNATED REVIEWERS

Designated Reviewing Organizations	POC
Sample Management (Champion)	J. G. Paetel
Quality Systems	J. E. Hyatt

9.0 REFERENCES

WHC-CM-4-2, *Quality Assurance Manual.*

Figure 1. Statement of Work for Hanford Analytical Laboratory Services Format Title Page.

XXX
STATEMENT OF WORK TITLE

STATEMENT OF WORK
XXX-SOW-97-XXXX
REVISION NUMBER
DATE

PREPARED BY:

Author's name, title, Sample Management	Date

APPROVALS:

Manager's name, manager, Sample Management	Date
QA Representative's name, Title, Organization	Date
Procurement Representative, Title, Organization (if required)	Date
Client Representative	Date
On-Site Laboratory Services (if needed)	Date

Figure 2.

XX-SOW-97-XXXX
Revision X

STATEMENT OF WORK
STATEMENT OF WORK TITLE

1.0 Services Required

The Services Required section describes the purpose, scope, and a summary of requirements for analytical laboratory services (requirements outline parameters of work to be completed).

2.0 Technical Requirements

Analytical laboratory testing requirements as developed from the customer are included in the Technical Requirements section. Analytical requirements may be specified by referencing standard methods and/or protocols or by listing specific analysis and required detection limits. Sample matrix, characteristics, and shipping, storage requirements are also addressed in this section.

3.0 Quality Assurance/Quality Control

The Quality Assurance/Quality Control section defines the requirements for the laboratory internal quality assurance program. The quality assurance section also describes other pertinent requirements such as, but not limited to, laboratory certifications, quality assurance program requirements, analysis and routine submittal of Performance Evaluation samples and/or laboratory interlaboratory comparison/results, quality assurance surveillances/audits, software control, etc.

Specific quality control requirements are defined in this section based upon the requirements presented to the SMO Project Coordinator by the Customer/Technical Coordinator.

4.0 Analytical Deliverables

The SOW Analytical Deliverables section describes the content of the sample analytical laboratory data package (hardcopy and electronic media). This section describes the level of reporting in relation to the applicable regulatory requirements or protocols by which the analysis were performed.

5.0 Document Control

This section describes the regulatory and customer (DOE, etc.) requirement for the control, maintenance, storage, retrieval, and turnover of records generated by the laboratory.

6.0 Sample Management

The Sample Management section describes the sample scheduling, shipment, receipt, analysis, and disposal or return to WMX. This section also details requirements concerning sample sizes, radioactivity level, and sample tracking system (chain-of-custody, sample receipt).

7.0 Contract Management and Deliverables

This section provides a summary of all required contractual and technical/administrative requirements. These requirements range from analytical deliverable schedule, reporting sample anomalies, loss of capability, case file maintenance, records disposition, monthly progress reporting, and other requirements as required for incorporation in the SOW.

8.0 Organization of Technical Proposal

Each SOW consists of an attachment entitled Organization of Technical Proposal describing to the laboratory the specific format, organization, and criteria in response to the SOW.

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Corrective Action Management

Approved by
J. E. Hyatt, Manager
Hanford Analytical Services

Author: J. G. Phelps
Organization: Operations Support

1.0 PURPOSE

This section provides direction for conducting, tracking, and closure activities associated with the correction of formally reported adverse conditions or deficiencies.

2.0 SCOPE

This section applies to all Hanford Analytical Services (HAS) facilities and organizations.

3.0 DEFINITIONS

Actionee
The individual assigned responsibility for preparing a corrective action plan and completing actions to correct a condition. The actionee may also be the condition owner.

Adverse Condition
Term applied to deviations, failures, malfunctions, deficiencies, defective items, and nonconformances in items or activities affecting quality, safety, health, operability, or the environment.

Condition Originator
The person or organization identifying an adverse condition that requires corrective action.

Condition Owner
The designated HAS manager with authority and responsibility to initiate and implement remedial and corrective action. The condition owner may also be the actionee.

Corrective Action Evaluation Group (CAEG)
Group trained to determine and assign Priority Planning Grid (PPG) and Root Cause Analysis (RCA) values to adverse conditions.

Corrective Action Management System (CAMS)
The system utilized to ensure adverse conditions are identified, tracked, and resolved.

Corrective Action Plan
A statement of the corrective action(s) to be taken to correct an adverse condition, include measures to preclude repetition or recurrence.

Database Administrator (DBA)
The individual responsible for entering and maintaining data in the Hanford Action Tracking System (HATS), for maintaining and issuing a monthly HATS report, and for maintaining and tracking the corrective action folders.

Hanford Action Tracking System (HATS)
The database used to manage internally and externally identified deficiencies and associated corrective actions. HATS is the only database to be used for tracking corrective actions within HAS.

Hanford Analytical Services (HAS) HATS Corrective Action Change Request Form
Form generated by the HAS Operations Support group for requests and justification, for approval of extensions of due dates, change of condition owner, or change of actionee.

Hanford Analytical Services (HAS) HATS Corrective Action Request Form
Form generated by the HAS Operations Support group for originating, tracking, and maintaining status of corrective actions.

Non-CAMS
A term used for actions that are tracked in the HATS database, but are not related to adverse conditions.

PPG
A graded approach to determine the extent of corrective action required for each adverse condition. Priority Planning Grid (PPG) meetings will be held by HAS CAEG to assign values to the condition in accordance with WHC-CM-1-4, *Corrective Action Management Manual*.

Source Document
Initiating document from the originator reporting the adverse condition. This is to include documents originated both internally and externally to HAS.

Trend Analysis

CAMS data shall be analyzed to identify trends that adversely impact quality and to identify opportunities and improve items and processes. Statistically significant trends shall be promptly reported to senior management.

4.0 RESPONSIBILITIES

4.1 Actionee

4.1.1 Prepares and implements corrective action plans for assigned conditions.

4.1.2 Provides current status and closure information to DBA for each assigned condition.

4.2 HAS Managers

4.2.1 Ensure timely resolution and correction of adverse conditions identified within their area of responsibility.

4.3 Condition Owner

4.3.1 Accepts overall responsibility for the processing of the specific adverse condition from discovery through verification, documentation of completion and closure of all remedial and corrective actions.

4.3.2 The condition owner will provide a lessons learned per WHC-CM-1-4, Corrective Action Management, and WHC-CM-1-5, *Standard Operating Practices*, before closure of the condition if the PPG value is evaluated at or higher than 25 and/or if the CAEG determines that the condition is sufficient to warrant a lessons learned.

4.4 Corrective Action Evaluation Group (CAEG)

4.4.1 The CAEG team members are responsible for evaluating assigned conditions and developing consensus on PPG relative risk values and assisting and/or providing RCA.

4.5 Database Administrator (DBA)

4.5.1 Inputs new assessments, surveillances, audits, and so forth, responses, actions, and any changes into the HATS database per the information originated in the HATS corrective action request form.

4.5.2 Maintains the record copy of the adverse condition corrective action file for each condition.

4.5.3 Chairs the HAS CAEG meetings.

4.5.4 Submits closed condition files to Records Holding Area/Management Information Systems (RHA/MIS) and to the Laboratory Technical Information Center (LTIC).

5.0 PROCEDURE

5.1 Determine Adverse Conditions Requiring Corrective Action

5.1.1 Adverse conditions shall be identified on source document and submitted to the HATS database administrator for data entry.

5.2 Complete HATS Data Entry

5.2.1 DBA shall enter data from source document using the HATS user's guide, WHC-SD-GN-CSUD-30013.

1. If source document is external to HAS, then data entry may be performed by non-HAS DBA.

5.3 Process HATS Data

5.3.1 DBA shall review HATS database regularly.

1. Identifies new entries.
2. Confirms condition owner accepts new adverse condition.
   (a) If rejected, then seek appropriate condition owner and complete proper documentation.
3. Acquires source document(s).
   (a) Submits copy to condition owner.
4. Verifies accuracy of HATS entry as compared to source document.

5.3.2 DBAs shall establish working folders with condition owner for each adverse condition.

1. Working folders will include a copy of the source documentation, adverse condition, Corrective Action Request form, and a Corrective Action Change Request.

5.3.3 DBAs shall establish record files for each adverse condition.

1. Record files will include a copy of the source document, adverse condition, PPG evaluation, Root Cause Analysis, lessons learned if applicable, and a closure statement.
2. Maintain documentation of activities through closure.

5.3.4 Actionee shall complete corrective action plan.

1. If adverse condition was identified by RL, then ensure within 30 days that the corrective action plan is written, submitted to RL and DBA, and entered into HATS.

2. If adverse condition was identified by PHMC, then ensure within 30 days that resolution or corrective action plan is written, submitted to DBA, and entered into HATS.

3. Condition Owners normally have 30 days to respond to adverse conditions. The response should be sent to the DBA, indicating the condition identifier (for example, IAA-95-0013-AUD-15), the action taken, and date completed.

   (a) If the response initiates actions to be completed in the future, actionees and estimated dates of completion must be included.

4. If there are any changes/revisions to the original corrective action plan throughout the CAM process, then a HAS HATS corrective action change form must be submitted to the DBA for HATS entry.

5.4 Process Flow

5.4.1 CAEG shall complete risk analysis of adverse condition.

5.4.2 The DBA shall submit the Corrective Action Request form to condition owner for identification of actionee. The condition owner has the option of assigning an action due date if resolution is required in a timely manner.

5.4.3 Actionee will sign the Corrective Action Request form accepting responsibility for the action(s) assigned by the condition owner and determine an action due date if not already noted.

NOTE: The CAEG team members will consist of the CAEG chairperson, and three other personnel trained in Priority Planning Risk evaluations and Root Cause Analysis. One of the three members will be from the HAS Quality Systems group.

1. Duties of CAEG Chairperson

   (a) determines additional CAEG attendance in addition to originator and condition owner

   (b) schedules CAEG meeting

   (c) distributes copies of applicable source document(s) to CAEG members.

2. CAEG determines PPG value according to WHC-CM-1-4.

   (a) The macro forms identified in the WHC-CM-1-4 for PPG and RCA will be used for formal evaluations and the PPG and RCA forms in the HATS system will be used for informal evaluations. Formal evaluations are PPG valued equal or greater than 11.

(b) Submits PPG risk evaluation form to assigned DBA.

NOTE: **Root Cause Analysis (RCA) is required for all identified conditions. If the PPG value is less than 11, HAS CAEG will assist the condition owner in determining the RCA. Root Cause 11 and over will be performed and documented in accordance with WHC-CM-1-4. The formal RCA will be prepared by trained RCA analysts.** If a lesson learned applies, it will be done in accordance with WHC-CM-1-5, **Section 14.1.**

5.4.4 Actionee shall implement corrective action plan.

1. As the actions are completed, condition owners/actionees shall notify the DBA. This information is to be documented via the HAS HATS corrective action request folder. The message should include action taken and the date completed. Also included should be any documentation to close action, (such as, Standing Order, procedures, copy of work package, etc.).

2. Actionee shall submit first extension requests to the Condition Owner for approval. All subsequent extension requests will be submitted to the Facility Manager for approval.

3. DBA tracks corrective action(s) through closure.

4. DBA maintains four in-boxes for dispositioning of HATS items: new items, action assigned and acceptance, change request, and closure.

5.5 Close Out Adverse Condition

5.5.1 Actionee shall complete corrective action(s).

5.5.2 Condition owner shall ensure corrective action(s) are verified complete.

5.5.3 Quality Systems shall verify all actions for closure with a graded approach value (PPG) of 25 or greater with random verification of 10% of action items between 11 and 25.

5.5.4 QS, Safety and RL will verify for closure when applicable.

5.5.5 Closure documentation is forwarded to DBA.

5.5.6 DBA shall enter data from the closure documentation provided in the HAS HATS corrective action request folders into the HATS.

5.6 Process Documentation

5.6.1 The DBA will generate a report the first part of each month, which will be issued to each responsible manager.

(a) Managers should review this report with their actionees to determine status of corrective actions assigned to their organization.

(b) Status of corrective actions on the monthly report will be identified with an "O" for open items, "E" for extensions, "V" for pending verification, or "D for delinquent.

5.6.2 DBA will provide monthly trending analysis reports (per direction of Quality Systems) to senior management and post graphs in 2704-S Performance Evaluation Board.

5.6.3 DBA shall maintain record files of all documentation associated with adverse condition until closure.

5.6.4 DBA shall submit closed condition file to RHA/MIS according to WHC-CM-3-5, *Document Control and Records Management Manual*, and to LTIC per WHC-CM-5-4, Section 7.2.

(a) Records that substantiate the completion of essential elements of the CAM System requirements for processing a condition are Quality Assurance Records and shall be retained in accordance with WHC-CM-3-5.

NOTE: **Condition owners/actionees are notified automatically by cc:Mail HATS notification under the following circumstances:**

- **When a new condition is assigned**
- **When there is a change of condition owner**
- **When there is a change of completion date**
- **When a condition becomes delinquent.**

6.0 RECORDS

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules, and Section 7.2 of this manual.

7.0 DESIGNATED REVIEWERS

Designated Reviewing Organizations	POC
Operations Support (Champion)	T. F. Dale
222-S Laboratory	J. R. Prilucik
WSCF	G. E. Millward
Quality Systems	J. E. Hyatt

8.0 REFERENCES

WHC-CM-1-4, *Corrective Action Management Manual.*

WHC-CM-1-5, *Standard Operating Practices*, Section 14.1, "Managing Lessons Learned."

WHC-CM-3-5, *Document Control and Records Management Manual*, Section 9.0, "Quality Assurance Records."

WHC-CM-4-2, *Quality Assurance Manual*, Section QI 16.1, "Trend Analysis."

WHC-CM-5-4, Laboratories Administration, Section 7.2, "Laboratory Records System."